Co-Sponsor the Griffith/Cuellar "The Preserving Patient Access to Compounded Medications Act"

Since passage of the Drug Quality and Security Act (DQSA) in 2013, the FDA has implemented and enforced the law in a way that is inconsistent with its congressional intent as has been expressed to the agency multiple times in the form of statements in the congressional record, letters from Congress, questions for the record asked in congressional hearings, directives in the reports accompanying FDA's appropriations bills, stakeholder input, and in some cases, the plain language of the statute. FDA's regulatory overreach has led to state licensed and compliant compounding pharmacies being inspected and otherwise treated like drug manufacturers, and more importantly, has jeopardized patient access to compounded medications.

For over three years, IACP has been working with a coalition of 30+ pharmacy and provider organizations who rely on compounded medications to treat their patients to try to work with the FDA and the Congress on improving the agency's compounding policies in a way that better balances public safety with patient access to critical medications. Unfortunately, despite these efforts, FDA continues to misinterpret the DQSA and assert regulatory authority over the practice of pharmacy and medicine in a way Congress never intended. Therefore, it is vital that Congress introduce and support legislation to clarify and "clean-up" the DQSA in a way that will better align the statute with congressional intent and better balance public safety and patient access.

Ask your Congressman to Co-Sponsor the Griffith/Cuellar "The Preserving Patient Access to Compounded Medications Act." This bipartisan legislation, introduced by Rep. Morgan Griffith (VA) and Rep. Henry Cuellar (TX), will clarify that the DQSA:

- Provides the records and registration exemptions provided to pharmacies under the Food Drug and Cosmetic Act when inspected by FDA to compounding pharmacies that are compliant with state and local pharmacy laws and 503A of the FDCA.
- Allows for "office-use" compounding of medications where authorized by state law.
- Allows for compounding with dietary supplements that comply with the monograph standards of the US Pharmacopoeia or National Formulary.
- Prevents FDA regulatory authority over interstate "dispensing" of compounded medications pursuant to prescriptions for identified patients, which is left to state law and state boards of pharmacy.
- Requires FDA to follow formal rulemaking procedures that allow stakeholder input and decrease confusion by providing formal FDA procedure and statements on the record. Currently, FDA is issuing "guidance documents" that FDA is enforcing through Warning Letters without following formal rulemaking procedures.

This legislation is needed to clarify the limits of FDA's regulatory authority of compounding pharmacies under the DQSA. Once enacted, the FDA, compounding pharmacies, medical providers and patients will have much greater certainty as to where the line between pharmacy compounding and drug manufacturing lies in a way that will better balance public safety and patient access to the medications they need. **To co-sponsor, have your Congressman's staff contact Kristin Seum with Rep. Griffith (VA).**